

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	*	MDL Docket No. 2004
		4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*	
		Case Nos.
LIABILITY LITIGATION	*	4:12-cv-176 (Taylor)
		4:13-cv-42 (Sanborn)
	*	4:14-cv-117 (Mack)

O R D E R

Mentor filed motions in limine in *Taylor* (4:12-cv-176), *Sanborn* (4:13-cv-42), and *Mack* (4:14-cv-117) to exclude evidence of ObTape complications in women other than Plaintiffs that Mentor contends are not sufficiently similar to the incidents experienced by Plaintiffs. Mentor also objects to any such evidence that is hearsay. As explained in the remainder of this Order, Mentor's motions are granted in part and denied in part.

The Court previously ruled that evidence of ObTape complications in patients other than Plaintiffs may be admitted for certain purposes if Plaintiffs demonstrate that the other incidents they seek to introduce are substantially similar to the Plaintiffs' injuries. Plaintiffs Teresa Taylor, Karen Sanborn, and Stephanie Mack proffered other similar incident evidence ("OSI") that they intend to offer at trial as proof that Mentor had notice of a defect in ObTape, the magnitude of the defect, Mentor's ability to correct the known defect, and

causation. The Court has reviewed the proffered OSI evidence and considered the parties' arguments. This Order describes the OSI evidence that the Court finds sufficiently similar to be admitted, assuming that it is not otherwise inadmissible.

DISCUSSION

I. Mentor's OSI Evidence Objections

"Evidence of similar occurrences may be offered to show a defendant's notice of a particular defect or danger, the magnitude of the defect or danger involved, the defendant's ability to correct a known defect, the lack of safety for intended uses, the strength of a product, the standard of care, and causation." *Hessen v. Jaguar Cars, Inc.*, 915 F.2d 641, 650 (11th Cir. 1990). Evidence of similar occurrences "is only admissible if conditions substantially similar to the occurrence" also caused the plaintiff's injury. *Id.* at 649; *cf. Ross v. Black & Decker, Inc.*, 977 F.2d 1178, 1185 (7th Cir. 1992) (finding that incidents which occurred after the plaintiff's incident with the same brand and model product were still "probative of the unreasonably dangerous design and condition of the" product and the cause of the incident that injured the plaintiff).

Plaintiffs intend to introduce evidence that they suffer pain and discomfort because the design and composition of the ObTape suburethral sling is not reasonably suited for a product

that is implanted in the human body. Their experts plan to opine that the bio-incompatibility of ObTape causes various complications, including pain, discomfort, erosion of the sling, and infection. Plaintiffs wish to introduce incidents of these types of complications that were experienced by other women who were implanted with ObTape. Mentor seeks to exclude other incidents involving erosion and infection because Plaintiffs did not point to medical evidence that they had an erosion or infection.¹

Mentor's argument imposes a "nearly identical incident" standard on OSI evidence. As the Court has observed before, the OSI must be *substantially similar* to the plaintiff's complication, but it need not be nearly identical to be admitted. *See, e.g., In re Mentor Corp. ObTape Transobturator Sling Products Liab. Litig.*, No. 3:07-CV-00101, 2010 WL 2196632, at *1 (M.D. Ga. May 28, 2010); *see also Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313 (11th Cir. 2000) (finding no abuse of discretion when district court admitted evidence of

¹ Taylor testified that her doctor told her in 2011 that she had a urethral erosion of ObTape. Taylor Dep. 32:9-18, ECF No. 106 in 4:12-cv-176. But Taylor's doctor testified that Taylor did not have any erosion of the ObTape and that he never told Taylor that she had an erosion. Vukovich Dep. 96:1-8, 97:14-23, 99:6-11, ECF No. 104 in 4:12-cv-176. Taylor's expert did not indicate in his expert report that Taylor had a urethral erosion. Def.'s Reply in Supp. of Mot. in Limine re Substantially Similar Incidents Ex. D, Porter Expert Report ¶¶ VII.21-VII.22, ECF No. 95-4 in 4:12-cv-176 (noting that ObTape removal left Taylor's urethral tissue "very thin" but stating nothing about an erosion).

similar implant ruptures even though the exact mechanism of rupture was not the same); *Worsham v. A.H. Robins Co.*, 734 F.2d 676, 689 (11th Cir. 1984) (finding that district court properly admitted testimony regarding a connection between a manufacturer's intrauterine device and "the same type of injury suffered by the plaintiff"); *cf. Jones v. Otis Elevator Co.*, 861 F.2d 655, 662 (11th Cir. 1988) (finding that evidence of incidents involving a "malfunction in the normal stopping device" of an elevator were sufficiently similar to the plaintiff's incident, even though the other incidents were not identical).

Here, Plaintiffs' experts opine that ObTape's physical characteristics make ObTape an unsuitable implantable medical device due to lack of biocompatibility. They maintain that ObTape's physical characteristics, which contribute to its bio-incompatibility, caused Plaintiffs' injuries, including pain and discomfort. According to Plaintiffs' experts, these same physical characteristics of ObTape causes erosions and infections. Thus, while Plaintiffs' injuries may not be exactly the same as the injury suffered by a woman who experienced an erosion or infection, Plaintiffs' injuries, according to their experts, were caused by the same mechanism that cause erosions and infections—the lack of biocompatibility of the ObTape suburethral sling. For these reasons, the Court concludes that

evidence of erosions and infections is sufficiently similar to Plaintiffs' injuries to be admitted.

In summary, for evidence of an ObTape complication to meet the "substantially similar" requirement, the complication must be (1) experienced by a woman who was implanted with ObTape (2) by the transobturator approach (3) to treat stress urinary incontinence and (4) caused by the physical characteristics of ObTape that Plaintiffs' experts opine make ObTape lack biocompatibility.

For the foregoing reasons, Mentor's objections to the following OSI evidence based on lack of similarity are overruled: P-157, P-922, P-287, P-304, P-328, P-331, P-346, P-371, P-388, P-445, P-463, P-474, P-503, P-535, P-542, P-553, P-583, P-587, P-589, P-594, P-613, P-615, P-637, and P-688. Mentor's "lack of similarity" objections are also overruled as to peer-reviewed, published scientific and medical journal articles that refer to erosion and infection rates.

In reviewing Plaintiffs' submissions, the Court observed that P-388 contains photographs of ObTape patients. The Court previously excluded photographs depicting non-Plaintiffs. *In re Mentor Corp. Obtape Transobturator Sling Products Liab. Litig.*, No. 2004, 2015 WL 7863032, at *4 (M.D. Ga. Dec. 3, 2015) [hereinafter Dec. 3, 2015 Order]. The photographs in P-388 (and

any other exhibit) shall not be admitted and shall not be shown to the jury.

The Court also finds that Plaintiffs' medical expert witnesses may testify about their patients' complications that were caused by ObTape's lack of biocompatibility. These witnesses include Dr. Porter, Dr. Cosson, Dr. Baum, Dr. Catherine Ortuno, Ms. Nathalie Gremaud, Dr. Siegel.²

The Court notes that some exhibits referred to in the pending motions were not included in the record. The Court could not locate P-829 and P-295; they were not part of Plaintiffs' exhibit submission (ECF No. 94 in 4:12-cv-176). Plaintiffs did submit an exhibit labeled P-295 (ECF No. 94-5 in 4:12-cv-176), but it is not a risk management report dated September 22, 2004 as Plaintiffs state in their brief; it is a press release dated February 20, 2004. Plaintiffs represent that most of the reports contained in P-829 and P-295 involve erosion, infection, and/or chronic pain. Mentor asserts that some of the reports are about issues that are not related to biocompatibility—like bladder perforation and broken/snapped

² The Court notes that Mentor objects to Dr. Porter's testimony in Sanborn and Mack because those Plaintiffs did not list Dr. Porter as a witness. As the Court previously observed with regard to another witness, Plaintiffs should have followed the rules regarding the formal identification of Dr. Porter as a witness. However, the Court finds that Mentor is well aware of the testimony and will not be unduly prejudiced if the Court excuses Plaintiffs' inadvertent failure to formally identify Dr. Porter within the deadline. Accordingly, that objection is overruled.

sling. Plaintiffs must redact any reports that do not relate to biocompatibility of ObTape.

With regard to P-171, Mentor asserts that the exhibit discusses the product SABRE, not ObTape. The Court previously ruled that evidence regarding SABRE is not relevant. Dec. 3, 2015 Order, 2015 WL 7863032, at *3. P-171 is thus excluded.

With regard to P-520 and P-538, these exhibits are emails regarding Mentor consultants who no longer use ObTape. But the emails do not report any specific similar incidents. Therefore, while they may be admissible for another purpose, they are not admissible as OSI evidence.

Mentor also points out that P-256 and P-416 are not reports of other specific incidents, but they focus on non-incident discussions. The Court could not locate these exhibits in the present record and thus could not evaluate them. Plaintiffs submitted an exhibit labeled P-256 (ECF No. 94-3 in 4:12-cv-176), but it is not an email and report dated November 5, 2004 as Plaintiffs state in their brief; it is a set of documents comparing ObTape to other slings. Plaintiffs submitted an exhibit labeled P-416 (ECF No. 94-12 in 4:12-cv-176), but it is not a report dated August 2005. Rather, it is an email chain from September 2004. Before Plaintiffs may introduce these exhibits as OSI evidence, Plaintiffs must proffer them to the Court.

II. Mentor's Hearsay Objections

Mentor also objects to the reports of complications in other patients as impermissible hearsay. Obviously, the Court's rulings that certain evidence is admissible as OSI evidence does not mean that Mentor is precluded from asserting other objections to the evidence, such as hearsay objections. Plaintiffs did not respond to Mentor's hearsay objections. Mentor concedes that if a substantially similar complication occurred before a Plaintiff's ObTape implant, then it may be admitted for the limited purpose of proving notice of a potential defect in ObTape. Post-implant evidence would also be admissible to establish notice if Plaintiffs have a continuing duty to warn claim. The Court notes that Sanborn does not have a continuing duty to warn claim. But as indicated in the final pretrial orders in the Taylor and Mack cases, they both have continuing duty to warn claims that remain pending for trial. Thus, the Court is a bit confused as to whether Mentor is asserting hearsay objections to OSI evidence in Taylor and Mack. Of course, if the OSI evidence is tendered only for the purpose of notice, then it would likely not be hearsay. The parties should submit a limiting instruction prior to trial for the Court to give regarding such OSI evidence that is admitted only

for notice purposes and not for the truth of the matter asserted.³

CONCLUSION

Mentor's Motion in Limine #3 to limit Evidence to Only Substantially Similar Incidents (ECF No. 65 in 4:12-cv-176; ECF No. 66 in 4:13-cv-42; ECF No. 50 in 4:14-cv-117) is granted in part and denied in part as set forth in this Order.

IT IS SO ORDERED, this 1st day of February, 2016.

s/Clay D. Land

CLAY D. LAND

CHIEF U.S. DISTRICT COURT JUDGE
MIDDLE DISTRICT OF GEORGIA

³ Plaintiffs are placed on notice that evidence of complication reports made by third parties such as doctors and ObTape patients shall not be admitted at trial unless Plaintiffs demonstrate that an exception to the hearsay rule applies or that the reports are not hearsay. These issues should be anticipated prior to the day that the evidence will be tendered so that they can be addressed by the Court at the end of the preceding trial day after the jury has been excused for the day. THE COURT DOES NOT WANT TO WASTE JURY TIME ARGUING ABOUT THESE TYPES OF EVIDENTIARY ISSUES.